

## § 1008.36

## 42 CFR Ch. V (10–1–00 Edition)

legal issues if necessary to respond to the advisory opinion request. For example, the OIG may require the use of appropriate medical reviewers, such as peer review organizations, to obtain medical opinions on specific issues.

(b) The time period for issuing an advisory opinion will be tolled from the time that the OIG notifies the requestor of the need for an outside expert opinion until the time the OIG receives the necessary expert opinion.

(c) Once payment is made for the cost of the expert opinion, as set forth in § 1008.31(e) of this part, either directly to the expert or otherwise, the OIG will arrange for a prompt expert review of the issue or issues in question. Regardless of the manner of payment, the expert's work and opinion will be subject to the sole direction of the OIG.

[62 FR 7357, Feb. 19, 1997, as amended at 63 FR 38325, July 16, 1998]

### Subpart D—Submission of a Formal Request for an Advisory Opinion

#### § 1008.36 Submission of a request.

(a) A request for a formal advisory opinion must be submitted in writing. An original and 2 copies of the request should be addressed to the headquarter offices of the OIG.

(b) Each request for an advisory opinion must include—

(1) To the extent known to the requestor, the identities, including the names and addresses, of the requestor and of all other actual and potential parties to the arrangement, that are the subject of the request for an advisory opinion;

(2) The name, title, address, and daytime telephone number of a contact person who will be available to discuss the request for an advisory opinion with the OIG on behalf of the requestor;

(3) A declaration of the subject category or categories as described in § 1008.5 of this part for which the advisory opinion is requested. To the extent an individual or entity requests an advisory opinion in accordance with §§ 1008.5(a)(3) or (a)(5) of this part, the requesting individual or entity should identify the specific subsections of sec-

tions 1128, 1128A or 1128B of the Act or the specific provision of § 1001.952 of this chapter about which an advisory opinion is sought:

(4) A complete and specific description of all relevant information bearing on the arrangement for which an advisory opinion is requested and on the circumstances of the conduct,<sup>1</sup> including—

(i) Background information,

(ii) For existing arrangements, complete copies of all operative documents,

(iii) For proposed arrangements, complete copies of all operative documents, if possible, and otherwise descriptions of proposed terms, drafts, or models of documents sufficient to permit the OIG to render an informed opinion,

(iv) Detailed statements of all collateral or oral understandings, if any, and

(v) If applicable, a designation of trade secrets or confidential commercial or financial information in the manner described in 45 CFR 5.65;

(5) Signed certifications by the requestor(s), as described in § 1008.37 of this part;

(6) A check or money order payable to the Treasury of the United States in the amount of \$250, as discussed in § 1008.31(b) of this part;

(7) A declaration regarding whether an advisory opinion in accordance with part 411 of this title has been or will be requested from HCFA about the arrangement that is the subject of the advisory opinion request; and

(8) Each requesting party's Taxpayer Identification Number.

(Approved by the Office of Management and Budget under control number 0990-0213)

[62 FR 7357, Feb. 19, 1997, as amended at 63 FR 38325, July 16, 1998]

#### § 1008.37 Disclosure of ownership and related information.

Each individual or entity requesting an advisory opinion must supply full and complete information as to the identity of each entity owned or controlled by the individual or entity, and of each person with an ownership or

<sup>1</sup>The requestor is under an affirmative obligation to make full and true disclosure with respect to the facts regarding the advisory opinion being requested.